REMARKS

After entry of this amendment, claims 1-23, 25, and 30-33 are pending, of which claims 4, 9-23, and 25 are withdrawn. Claims 26-29 have been cancelled without prejudice or disclaimer. The subject matter of claim 26 has been incorporated into claim 8. The subject matter of claims 27 and 28 has been incorporated into claim 9. The subject matter of claim 29 has been incorporated into claim 25. New claims 30-33 have been added and find support *inter alia* in the original claims. Further support for the newly added claims is found in the specification at page 22, lines 7-12, and page 34, lines 10-17. Claims have been amended without prejudice and disclaimer to delete the non-elected subject matter and to better comply with the U.S. practice. The amended claims find support *inter alia* in the original claims. Claims 1 and 12 find further support in the specification at page 22, lines 7-12, and page 34, lines 10-17. No new matter has been added.

Withdrawn method claims have also been amended to depend from the elected product claim or otherwise require all the limitations of the product claims. Support is found *inter alia* in the original claims. No new matter has been added. In the event that the product claim is found allowable, rejoinder of the withdrawn method claims is respectfully requested. MPEP § 821.04(b).

Drawings

The Examiner objects to the drawings for lack of a Brief Description of the Drawings.

In response, a section entitled "BRIEF DESCRIPTION OF THE DRAWINGS" has been inserted in the specification at page 6 to provide proper figure legends as required by the Examiner. Support is found *inter alia* in the specification and in the drawings as originally filed. No new matter has been added.

Abstract

The Examiner objects to the abstract for containing more than one paragraph and legal phraseology.

Applicants respectfully submit herewith an amended abstract in a separate sheet pursuant to 37 C.F.R. § 1.72. The amended abstract finds support in the abstract as originally filed. No new matter has been added.

Sequence Rules

The Examiner requires that the sequences at pages 44-45, 50-51, and 58-59 be identified by sequence identifying number and be included in the Sequence Listing. It is respectfully submitted that the sequence identifying numbers for those sequences have been already added into the specification in the Preliminary Amendment dated August 26, 2005 and the sequences have been included in the Sequence Listing of record. Withdrawal of this objection is respectfully requested.

However, upon review of the application, Applicants note that two sequences appearing in Figure 1 were not included in the Sequence Listing. Applicants submit herewith a replacement copy of the Sequence Listing that conform to 37 CFR §§ 1.821-1.825 in electronic format as text file *via* EFS-Web accompanied by a Statement to Support Filing and Submission in Accordance with 37 CFR §§ 1.821-1.825. The corresponding sequence identifiers have also been added to the brief description of Figure 1 to comply with 37 CFR § 1.821(a) and (d). The specification has also been amended adding the required paragraph to incorporate by reference the text file of the Sequence Listing submitted *via* EFS-Web as per 37 CFR § 1.52(e)(5). No new matter has been added to the Sequence Listing. Entry of this Sequence Listing into the application is requested.

Claim Objection

Claim 2 is objected to as being improper dependent form for failing to further limit the subject matter of claim 1 and for reciting non-elected sequences. It is believed that the objection is rendered moot in light of the present amendment. Reconsideration and withdrawal of the objection is respectfully requested.

Claim Rejections – 35 USC § 112, First Paragraph

Claims 1, 3, 5-8 and 26 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and lack of an enabling disclosure. Applicants respectfully disagree. However, to expedite prosecution, claim 1 has been amended without prejudice or disclaimer to recite the percent identity as 80%. Applicants respectfully submit that claim 1 as amended overcomes both rejections.

Written Description Rejection

The Examiner alleges that claims 1 and 3 lack defined structure of the claimed nucleic acids and SEQ ID NO: 1 is not representative of the claimed genus. The Examiner further asserts that claims 5-8 and 26 encompass genomic sequences which are allegedly not disclosed in the specification. To address these concerns, Applicants have amended the claims without prejudice or disclaimer to recite the acyl-CoA:lysophospholipid-acyltransferase (LPLAT) with more specificity based on percent identity to the recited SEQ ID NO: 1 or 2. Specifically, claim 1 has been amended to recite the LPLAT encoding nucleotide sequence based on the sequence of SEQ ID NO: 1, or the encoded LPLAT polypeptide sequence based on the sequence of SEQ ID NO: 2, and variants having at least 80% identity to SEQ ID NO: 1 or 2. It is respectfully submitted that the specification provides sufficient written description for the claimed genus as defined by the amended claims.

The guidelines for applying the written description requirement is stated in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, 1, Written Description Requirements" 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). As there indicated, the written description requirement as applied to a claim reciting a genus can be satisfied in a number of alternative ways, such as through sufficient description of a representative number of species, by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

Furthermore, as stated in *Eli Lilly and Co.*, "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs." 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). As the Examiner acknowledged, the specification discloses additional DNA sequences that encode LPLAT, namely SEQ ID NOs: 3, 5, 7, and 34 (nucleotide 2805-3653, see page 59, lines 15-16). These sequences share more than 80% identity with SEQ ID NO: 1. Similarly, the polypeptide sequences encoded by these nucleotide sequences share more than 80% identity with SEQ ID NO: 2. These **five** sequences are clearly representative of the genus being claimed.

Because each and every embodiment within a claim need not be disclosed, it is submitted that the specification provides a representative number of species under the standard of *Eli Lilly and Co. See also In re Angstadt*, 537 F.2d 498 (CCPA 1976) (holding that there has never been

a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example). Accordingly, it is respectfully submitted that the claims as amended satisfy the written description requirement.

Reconsideration and withdrawal of the rejection is respectfully requested.

Enablement Rejection

The Examiner further rejects the claims for lack of enablement, alleging that the specification does not enable the variants or homologs of SEQ ID NO: 1 or 2. The Examiner contends that it is not routine in the art to screen for multiple substitutions or modifications and the result of such modifications is unpredictable. Additionally, the Examiner asserts that the specification does not provide regions of the protein structure that may tolerant modifications and guidance for modifying a protein with expectation of obtaining desired enzymatic activity. Applicants respectfully disagree and traverse the rejection.

As disclosed at pages 50-60, the specification provides detailed description including working examples on how to clone a LPLAT gene (Example 2) and how to test its activity in producing the desired product in yeast and plant (Example 4). Furthermore, the specification discloses conserved regions of LPLAT (Figure 1), within which one skill in the art would know to avoid any substitutions or modification. As mentioned above, the specification discloses multiple actual sequences. In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claim without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

This analysis is in consistent with the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007)(hereinafter "*Kubin*"), where the Board held that a claim encompassing 80% amino acid sequence identity to the disclosed sequence was fully enabled. *Kubin* at 1416. As the Board noted in *Kubin*, even though practicing the full scope of the claims might have required extensive experimentation, the experimental techniques were well-known in the art, so the experimentation would have been routine and thus, not undue. *Id.* at 1416.

As in *Kubin*, the experimentation required to practice the present claims (making and screening mutant sequences) is routine in nature and clearly not "undue." Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejection – 35 USC § 112, Second Paragraph

The Examiner rejects claims 1, 3, 5-8 and 26 under 35 USC § 112, second paragraph, as being unclear as to what the "C16, C18-, C20- or C22-fatty acids" compounds are converted to. Applicants respectfully disagree and traverse the rejection.

As stated in § 2173.02 of the M.P.E.P. "[t]he test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed *when the claim is read in light of the specification.*'" (M.P.E.P. § 2173.02, emphasis added) If one skilled in the art is able to ascertain the meaning of the terms in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. See M.P.E.P. § 2173.02.

The activity of the polypeptides encoded by the claimed nucleotides are well described throughout the specification, for example, at page 34, line 40 through page 36, line 26. Particularly, these polypeptides possess acyl-CoA:lysophospholipid-acyltransferase activity and are involved in the metabolism of lipids and fatty acids. As described in the paragraph bridging pages 35 and 36, substrates of the acyl-CoA:lysophospholipid acyltransferases may be C16-, C18-, C20- or C22-fatty acids to produce C18-, C20- or C22-fatty acids with at least two double bonds in the fatty acid molecule. Thus, it is clear to one skilled in the art that the product of the polypeptides encoded by the claimed nucleotides depends on the substrate used. Accordingly, Applicants respectfully submit that the claims are clear when read in view of the specification, and therefore, satisfy the requirements under 35 USC § 112, second paragraph.

Claim Rejection – 35 USC § 102(b)

Claims 1, 3, 5, 8 and 26 are rejected under 35 USC § 102(b) as being anticipated by Cases et al. ("Cases," PNAS, 1998, 95: 13018-13023).

Cases discloses a gene encoding an acyl CoA:diacylglycerol acyltransferase from mouse, an enzyme involved in triacylglycerol synthesis by using diacylglycerol and fatty acyl CoA as substrates, while the present application claims acyl-CoA:lysophospholipid-acyltransferase from *C. elegans*. Furthermore, a sequence alignment demonstrates that the acyl CoA:diacylglycerol

acyltransferase disclosed in Cases is not within the scope of the present claims as amended. It is therefore respectfully submitted that, in view of the present amendment, the reference cited by the Examiner does not anticipate the claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Applicants are submitting their response within the three-month response period. No fee is believed due. However, if any fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00119-US from which the undersigned is authorized to draw.

Respectfully submitted,

By _____

Hui-Ju Wu, Ph.D.
Registration No.: 57,209
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141
(302) 658-5614 (Fax)
Agent for Applicants

585254